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No. 09-1351

# In the Supreme Court of the United States

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC., ET AL., PETITIONERS

*v.*

FOOD AND DRUG ADMINISTRATION, ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT*

## BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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## QUESTIONS PRESENTED

1. Whether petitioners lack standing to challenge the Food and Drug Administration's decision to make the "Plan B" emergency contraceptive drug available without a prescription to women age 18 and older.

2. Whether petitioners must exhaust mandatory administrative remedies before bringing suit.

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# In the Supreme Court of the United States

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*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT*

## BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

### OPINIONS BELOW

The judgment order of the court of appeals (Pet. App. 1a-4a) is unreported. The opinion of the district court (Pet. App. 5a-37a) is reported at 539 F. Supp. 2d 4. The order of the district court denying petitioners' motion for reconsideration (Pet. App. 38a-43a) is unreported.

### JURISDICTION

The judgment of the court of appeals was entered on November 27, 2009. A petition for rehearing was denied on February 3, 2010 (Pet. App. 45a). The petition for a writ of certiorari was filed on May 4, 2010. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATEMENT

Petitioners are associations of physicians, pharmacists, and nurses seeking to challenge a decision of the Food and Drug Administration (FDA) permitting the sale of the emergency contraceptive levonorgestrel (marketed as "Plan B") without a prescription to women age 18 and older. The questions presented are whether petitioners have standing to challenge FDA's action, and whether they must first exhaust mandatory administrative remedies.

1. Under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, the manufacturer of a new drug must submit a new drug application (NDA) to FDA and obtain the agency's approval before marketing the drug in the United States. 21 U.S.C. 355(a) and (b). FDA approval of an NDA requires the manufacturer to establish, *inter alia*, that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling," and "that the drug will have the effect it purports or is represented to have." 21 U.S.C. 355(d).

Some drugs are approved for dispensing only by prescription (and thus known as "Rx-only") because their "toxicity or other potentiality for harmful effect, or the method of [their] use, or the collateral measures necessary to [their] use," makes them "not safe for use except under the supervision of a [health care] practitioner." 21 U.S.C. 353(b)(1)(A). A drug initially approved as Rx-only may later be "switched" to over-the-counter (OTC) dispensing if FDA finds that the prescription requirements are no longer warranted for public health reasons and the drug is "safe and effective for use in self-medication as directed in proposed labeling."

21 C.F.R. 310.200(b); see 21 U.S.C. 353(b)(3), 355(c) and (d).

A switch from Rx-only to OTC dispensing may be requested in two distinct ways. The manufacturer may ask for such a switch by submitting a supplemental new drug application (SNDA). 21 C.F.R. 310.200(b). Or any other "interested person" may petition for a switch pursuant to 21 C.F.R. 10.25(a). See 21 C.F.R. 310.200(b). Section 10.25(a) provides more generally for interested persons to "petition the Commissioner [of FDA] to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. 10.25(a); see 21 C.F.R. 10.30 (providing form for such a "Citizen Petition").

Under FDA's regulations, a person who does not file a citizen petition or an SNDA may not seek judicial review of an FDA determination on an Rx-to-OTC switch. Rather, FDA regulations prescribe an exhaustion requirement: "[a] request that the Commissioner take or refrain from taking any form of administrative action *must first* be the subject of a final administrative decision based on a petition submitted under [21 C.F.R.] 10.25(a) * * * before any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. 10.45(b) (emphasis added).

2. On July 28, 1999, FDA approved an NDA for prescription Plan B. Pet. App. 7a. In April 2003, Plan B's manufacturer submitted an SNDA requesting that the drug be made available OTC. *Id.* at 7a-8a. By letter, FDA informed the manufacturer, then Duramed Pharmaceuticals, Inc., that the SNDA was not approvable because Duramed had not provided data sufficient to show that Plan B was safe for OTC use by young adolescent women. *Id.* at 8a. FDA suggested that Duramed either

provide data to demonstrate that consumers under the age of 16 could safely use Plan B as an OTC drug, or else seek OTC status only for sales to women over the age of 16. *Ibid.*

Duramed submitted an amended SNDA, seeking an Rx-to-OTC switch only for women age 16 and older. Pet. App. 8a. FDA found Plan B to be safe for OTC use for women age 17 and older, but it did not immediately approve such distribution. *Ibid.* FDA instead published an Advance Notice of Proposed Rulemaking (ANPRM), seeking public comment on whether it could in general approve distribution of the same drug to different populations for Rx-only and OTC use, and whether it should conduct further rulemaking to clarify its authority to do so. *Ibid.* (citing 70 Fed. Reg. 52,050 (2005)). After reviewing approximately 47,000 comments, FDA determined that further rulemaking was unnecessary. *Id.* at 9a.

In August 2006, Duramed submitted a second amended SNDA, requesting OTC availability of Plan B for women age 18 and older. Pet. App. 9a. In its application, Duramed proposed a single package for Plan B to be used for both the Rx and OTC populations, bearing the legend "Rx only for age 17 and younger." *Ibid.* Duramed indicated that Plan B would only be available "behind the counter" at licensed pharmacies and health care clinics. *Ibid.* FDA approved the second amended SNDA later that month, thus permitting OTC access to Plan B for women age 18 and older. *Ibid.*[1]

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[1] Subsequently, in litigation brought following a citizen petition by groups unrelated to petitioners, the United States District Court for the Eastern District of New York directed FDA to change the minimum age for OTC access to Plan B from 18 to 17. See *Tummino* v. *Torti*, 603 F. Supp. 2d 519 (2009). FDA has complied by approving the OTC

3. On April 12, 2007, petitioners filed a complaint in district court seeking to vacate FDA's August 2006 SNDA approval decision.[2] Pet. App. 9a. The district court dismissed petitioners' amended complaint for want of standing, and held, in the alternative, that they had failed to exhaust mandatory administrative remedies under the FDCA. *Id.* at 13a.

a. The district court rejected each of the six theories of injury petitioners advanced in support of their claim of standing. First, the court concluded that petitioners suffered no cognizable "[i]nformational injury." Pet. App. 18a. The court explained that such injury arises "only in very specific statutory contexts where a statutory provision has explicitly created a right to information," and the FDCA is not such a scheme because it "does not confer a broad, legally enforceable right to information." *Id.* at 18a-19a (internal quotation marks and citations omitted). Moreover, the court noted, petitioners alleged not that they were "deprived of information to which they are legally entitled," but rather that "their members may be misled based upon the efficacy information that is contained on Plan B's labeling." *Id.* at 20a-21a. And in any event, the court noted, that alleged informational injury could not be redressed by undoing the Rx-to-OTC switch, because Plan B would

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sale of Plan B to women age 17 and older. See HHS, *NDA Approval Letter* (July 2009), http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/021998s000ltr.pdf.

[2] In addition to petitioners, plaintiffs below included Family Research Council (FRC). At oral argument in the district court on February 15, 2008, both FRC and Concerned Women for America—a petitioner in this Court—conceded that they lacked standing. See Pet. App. 17a.

still carry the same safety information, even if it were available only by prescription. *Id.* at 21a.

Second, the court found that petitioners conceded they could not demonstrate injury sufficient to support their theory of standing based on an allegedly increased risk of harm for adult consumers of Plan B. Pet. App. 22a-23a.

Third, the district court held that the petitioner associations of physicians could not establish "competitive" standing based on lost revenue from office visits by patients age 18 and older who had previously needed to obtain a prescription to buy Plan B. Pet. App. 23a. The court found this alleged harm "purely hypothetical and speculative," because petitioners did not allege that any physician had lost revenue when Plan B became available OTC to women age 18 and older. *Ibid.* The court further held that plaintiffs could not establish the causation required for Article III standing, because "[n]othing in the FDA's approval * * * forbids a woman from first consulting with her doctor before obtaining Plan B, even if it is sold OTC," making "any loss of revenue suffered by physicians * * * attributable to the independent choices of [their patients]." *Id.* at 23a-24a. The court further found that even if petitioners had established constitutional standing on their "competitive injury" claim, principles of prudential standing would bar their challenge because petitioners' economic well-being is not within the zone of interests of the FDCA provisions allowing OTC sale of certain drugs. Those provisions were designed "to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician." *Id.* at 24a (quoting S. Rep. No. 946, 82d Cong., 1st Sess. 1-2 (1951) (*Sen-*

*ate Report*)). The district court explained that petitioners' claimed interest in additional office visits was "antithetical" to that statutory purpose. *Id.* at 25a.

Fourth, the district court rejected the physician association petitioners' contention that they had standing to assert their members' patients' interests. Pet. App. 27a. The court found that petitioners could not meet the requirements for third-party standing, because petitioners did not allege a sufficient injury of their own, and failed to establish that their patients were hindered from asserting their own rights. *Id.* at 26a-27a.

Fifth, the district court rejected petitioners' argument that they have standing to challenge FDA's approval of OTC distribution of Plan B to women age 18 and older because it will (1) subject their member pharmacists to increased risk of liability for selling a misbranded drug; (2) create additional administrative burdens for those pharmacists; and (3) compel pharmacists' speech notwithstanding their conscience-based objections. Pet. App. 27a-28a. The court found the suggestion that pharmacists would be subjected to liability for selling Plan B OTC with FDA authorization to be "'imaginary or speculative,'" inasmuch as "there has been no determination that Plan B is misbranded." *Ibid.* (quoting *Babbitt* v. *United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). The court similarly rejected the argument that FDA's determination would create additional administrative burdens for pharmacists; not only did petitioners fail to allege any such burden, but also "[l]ogically, it seems as though the administrative burdens of pharmacists would have decreased after the FDA approved the SDNA," because prescription sales involve more paperwork than OTC sales. *Id.* at 29a. The district court further found that it "need not linger

long" on petitioners' compelled-speech argument because FDA does not force any pharmacist to sell Plan B. *Ibid.*

Finally, the district court rejected petitioners' theory of "procedural" standing, which asserted that they "were denied the opportunity to participate in notice-and-comment rulemakings for the Rx-to-OTC switch for Plan B" when FDA did not use rulemaking to approve the SNDA. Pet. App. 30a. The court found this claim wanting because petitioners identified no concrete injury to a legally protected interest of either the organizations themselves or their members, and because petitioners failed to show a sufficient causal connection between the alleged procedural violation and any such injury. *Id.* 30a-31a.

b. In the alternative, the district court held that petitioners failed to exhaust mandatory administrative remedies before filing suit, as required by 21 C.F.R. 10.45(b). Pet. App. 31a-32a. The court rejected petitioners' argument that an agency may not require exhaustion by regulation, noting that this Court's decision in *Darby* v. *Cisneros*, 509 U.S. 137, 153 (1993), held that "the exhaustion doctrine continues to exist under the APA to the extent that it is required by statute or by *agency rule* as a prerequisite to judicial review." Pet. App. 32a. The court also rejected petitioners' contention that FDA's regulations do not require exhaustion before filing suit; petitioners' proposed reading of the regulations, the district court explained, "would undermine the entire regulatory process." *Id.* at 33a (internal quotation marks and citation omitted). The court also found "no circumstances that should lead [it] to decline to require exhaustion." *Id.* at 37a.

c. Petitioners sought reconsideration. The district court denied that relief, noting that petitioners "mainly used their motion for reconsideration as an inappropriate vehicle to reargue facts and theories upon which [the] court has already ruled." Pet. App. 39a (internal quotation marks and citation omitted). The court rejected petitioners' only new argument, an alleged "civil procedure" injury, and it noted that petitioners still failed to allege exhaustion, despite "ample opportunity" to "provide the necessary promised evidence" of their alleged exhaustion. *Id.* at 41a.

4. The court of appeals affirmed in an unpublished per curiam judgment order, stating that the "District Court's decision needs no amplification," Pet. App. 3a. It agreed with the district court that petitioners' numerous theories of standing were wanting, and that petitioners failed to exhaust mandatory administrative remedies. *Id.* at 3a-4a. Even assuming they had standing, the court of appeals explained, petitioners were required to file a citizen petition before coming to court, but failed to do so, and "proffered no legally viable excuse for this failure." *Id.* at 4a.

## ARUGMENT

Petitioners contend that the courts below erred in dismissing their amended complaint for lack of standing and failure to exhaust mandatory administrative remedies. The district court's reasoning is correct, and the court of appeals' summary affirmance was appropriate. The decision below does not conflict with any decision of this Court or of another court of appeals. Further review is unwarranted.

1. The district court and court of appeals correctly rejected petitioners' myriad theories of standing.

a. This Court has explained that under Article III of the Constitution,

> the irreducible constitutional minimum of standing contains three elements. First, the plaintiff must have suffered an "injury in fact"—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

*Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992) (internal quotation marks, alterations, and citations omitted).

There is in addition a prudential dimension to standing. Among other things, a plaintiff must show that the "interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute * * * in question." *Association of Data Processing Serv. Orgs.* v. *Camp*, 397 U.S. 150, 153 (1970). In that inquiry, the relevant zone of interests is "determined not by reference to the overall purpose of the Act in question * * * , but by reference to the particular provision of law upon which the plaintiff relies." *Bennett* v. *Spear*, 520 U.S. 154, 175-176 (1997).

b. Petitioners assert (Pet. 13-16) they have "informational standing" to challenge the FDA's determination to permit OTC sales of Plan B to women age 18 and

older. The district court correctly rejected that theory as "overly expansive and unsupported by the case law." Pet. App. 19a.

"Informational" injury is a form of Article III injury-in-fact that exists only "when the plaintiff fails to obtain information which must be publicly disclosed pursuant to a statute." *FEC* v. *Akins*, 524 U.S. 11, 21 (1998). This Court has found allegations of informational injury sufficient to confer standing only in a narrow class of cases in which agency action has completely deprived a plaintiff of a category of information that he is entitled by statute to receive. In *Akins*, for example, the Federal Election Commission's (FEC) determination that a particular group was not a "political committee" deprived the plaintiffs of information that the group would have been required to disclose by law if the FEC had classified the group as a "political committee." *Ibid.* Similarly, in *Public Citizen* v. *Department of Justice*, 491 U.S. 440, 449-450 (1989), the Court held that the plaintiffs had standing to challenge the government's (and the American Bar Association's (ABA)) refusal to disclose the names of potential judicial nominees being evaluated by the ABA Standing Committee on the Federal Judiciary, minutes of the Committee's meetings, and advance notice of future meetings; the Court reasoned that the plaintiffs asserted a right to that information under the Federal Advisory Committee Act and the Freedom of Information Act. *Ibid.* Likewise, in *Havens Realty Corp.* v. *Coleman*, 455 U.S. 363, 373-374 (1982), the Court found informational standing where the plaintiff was allegedly given false information in direct violation of a provision of the Fair Housing Act that prohibited such statements.

Here, by contrast, petitioners do not contend that they were denied a right to statutorily required drug labeling information. Rather, they assert that the drug labeling information that was provided might mislead their members. Unlike the defendant agencies in this Court's informational-injury cases, FDA has not denied petitioners labeling information they are entitled to receive; at most, it has determined (against petitioners' view of the matter) that Plan B is safe for use without a prescription in some circumstances. If that policy disagreement were sufficient to create informational injury, the narrow doctrine surrounding informational injury would balloon into a theory under which plaintiffs could assert all manner of generalized grievances against the government, notwithstanding this Court's repeated holdings to the contrary. See, *e.g.*, *Defenders of Wildlife*, 504 U.S. at 573. Petitioners cite no case from any court of appeals holding that the FDCA creates an informational right sufficient to support standing under the circumstances here.

Furthermore, petitioners' alleged informational injury would not be redressed by vacating the FDA's decision allowing OTC sale of Plan B to some consumers. The drug's labeling—which is what petitioners attack in their amended complaint (*e.g.*, ¶ 17)—would be substantively the same regardless of whether the drug is dispersed OTC or, as they would prefer, only by prescription.[3] "[P]ut[ting] the parties back in the position they should have been in all along," Pet. 16 —*i.e.*, with the manufacturer's Rx-to-OTC petition still pending—

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[3] Compare http://www.accessdata.fda.gov/drugsatfda_docs/label/1999/21045lbl.pdf (1999 approved labeling for Rx-only), with http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021045s011lbl.pdf (2006 approved labeling for dual Rx and OTC use).

would not address the putative flawed labeling information on which petitioners base their claim of injury.[4]

c. Petitioners contend (Pet. 16-18) they have "[c]ompetitive [s]tanding" on the theory that their member physicians are deprived of the revenues from office visits previously required to obtain Plan B prescriptions. That argument lacks merit, and petitioners concede that "[t]he circuits are in agreement with the law of the D.C. Circuit [on competitor standing]," Pet. 17; they argue only that the court of appeals misapplied its own precedent.

i. Petitioners fail to identify any concrete competitive injury. Even though Plan B had been available over-the-counter for a year before they filed their amended complaint, petitioners did not allege that a single member physician suffered actual economic harm as a result. Pet. App. 23a. Nor can petitioners establish that any such harm would be traceable to FDA's decision, or redressable by a decision in their favor, because any lost office-visit revenue would be attributable to the independent decisions of patients who now may choose whether or not to consult their doctor before using Plan B. See *id.* at 23a-24a (citing *Defenders of Wildlife*, 504 U.S. at 562).

ii. Even if petitioners could establish injury-in-fact, causation, and redressability on their theory of competitive injury, they would still lack standing because their physician members' economic well-being is not within

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[4] Petitioners' citation (Pet. 16) to recent amendments to the Pediatric Research Equity Act of 2003, Pub. L. No. 108-155, 117 Stat. 1936, is irrelevant. As the district court recognized, those amendments do not apply to SDNAs, like Duramed's, that were filed before September 27, 2007. See Pet. App. 21a n.3; see also 21 U.S.C. 355c(a)(1) (Supp. III 2009).

the zone of interests protected by the relevant provisions of the FDCA. The purpose of the FDCA provisions allowing OTC sales was "to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician." Pet. App. 24a (quoting *Senate Report* 1-2). As the district court recognized, petitioners' "alleged interest in generating fees from unnecessary doctor visits is *antithetical* to the purposes of the FDCA." *Id.* at 25a (internal quotation marks and citation omitted) (emphasis added). This Court has consistently found parties like petitioners, whose "interests are * * * inconsistent with the purposes implicit in the statute," to lack prudential standing. *Clarke* v. *Securities Indus. Ass'n*, 479 U.S. 388, 399 (1987).

Petitioners argue that their member physicians and pharmacists are nonetheless within the "zone of interests" of the FDCA's provisions requiring clear drug labeling. Pet. 22. Assuming *arguendo* that they are correct, it would not confer standing on them as *competitors*, and that theory would be related to no injury redressable in this case, see p. 12, *supra*. Parties are not free to mix-and-match one interest or injury for purposes of establishing Article III standing and a different interest or injury for the zone-of-interest test. See, *e.g.*, *Mountain States Legal Found.* v. *Glickman*, 92 F.3d 1228, 1232 (D.C. Cir. 1996) ("[O]n any given claim the injury that supplies constitutional standing must be the same as the injury within the requisite 'zone of interests' for purposes of prudential standing.").

Petitioners also suggest (Pet. 21) that FDA waived the zone-of-interests test's prudential limit on federal jurisdiction in a 1975 preamble to a *Federal Register*

notice. But they provide no support for the suggestion that parties can create standing in this way. Cf. *Vaden* v. *Discover Bank*, 129 S. Ct. 1262, 1269 (2009) ("[A] party may not create jurisdiction by concession.") (quotation marks and citation omitted). Nor can petitioners sidestep the zone-of-interests test by labeling the agency's actions *ultra vires*. See Pet. 23-24. Because such a claim must rest on an "officer's lack of delegated power," "[a] claim of error in the exercise of that power is therefore not sufficient" to allege *ultra vires* action. *Pennhurst State Sch. & Hosp.* v. *Halderman*, 465 U.S. 89, 101 n.11 (1984) (quoting *Larson* v. *Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 690 (1949)). Here, FDA has undisputed authority to approve Rx-to-OTC switches, and the district court correctly recognized that petitioners merely allege error in the exercise of an agency's delegated authority. See Pet. App. 25a n.4.

d. Finally, petitioners cannot establish standing based on a supposed "procedural injury." Petitioners appear to contend (see Pet. 7-10, 19-20) that FDA was required to conduct a formal rulemaking to approve the particular Rx-to-OTC switch for Plan B, and that any person has standing to assert that the failure to conduct such a rulemaking violates his rights. That argument is meritless, and petitioners do not contend there is a division of authority in the courts of appeals.

i. Petitioners argue that the courts below erred by failing to allow a "relaxed showing on immediacy and redressability" in the context of a claim of procedural injury. Pet. 20. That mischaracterizes the decisions below. The district court recognized that, in procedural injury cases, "the primary focus of the standing inquiry is not the imminence or redressability of the injury to the plaintiff, but whether a plaintiff who has suffered

personal and particularized injury has sued a defendant who has caused that injury." Pet. App. 30a (quoting *Florida Audubon Soc'y* v. *Bentsen*, 94 F.3d 658, 664 (D.C. Cir. 1996)). The court rejected petitioners' proffered procedural injury because they had not "identified a legally protected interest that has been infringed by these alleged procedural shortcomings," *ibid.*, even though it was their burden to demonstrate that the alleged procedural error "has 'demonstrably increased [the] risk of serious * * * harm' that 'actually threatens the plaintiff's particular interests,'" *id.* at 29a (quoting *Florida Audubon Soc'y*, 94 F.3d at 667); see *Summers* v. *Earth Island Inst.*, 129 S. Ct. 1142, 1151 (2009) ("Only a 'person who has been accorded a procedural right to protect *his concrete interests* can assert that right without meeting all the normal standards for redressability and immediacy.'") (quoting *Defenders of Wildlife*, 504 U.S. at 572 n.7).

ii. In any event, petitioners are incorrect on the merits; no rulemaking was required. The FDCA allows, but does not require, rulemaking to approve an Rx-to-OTC switch. FDA may either initiate rulemaking pursuant to 21 U.S.C. 353(b)(3), or it may approve a drug application submitted by a manufacturer requesting such a switch pursuant to 21 U.S.C. 355. See 21 C.F.R. 310.200(b). FDA's review of a drug application is an informal adjudication and does not require rulemaking. See 21 U.S.C. 355(c) and (d) (describing procedures applicable to drug application proceeding); 21 C.F.R. 314.71 (providing that drug application procedures apply to supplemental drug applications). Thus, when—as here—a manufacturer requests an OTC approval through a drug application, FDA decides that issue as part of the drug application process without

conducting rulemaking. That has been the FDA's consistent practice with respect to scores of OTC approval decisions over a period of four decades. Thus, even if petitioners had identified some concrete injury underlying their claim of procedural standing, their claim would have summarily failed on the merits. This case would therefore be an inappropriate vehicle for addressing any question of standing in a case where a plaintiff asserts a denial of procedural rights.

2. In all events, petitioners failed to exhaust their mandatory administrative remedies. See Pet. App. 3a-4a, 31a-37a. That was an independently sufficient basis for dismissing the case below, and would be an independent reason for this Court to affirm the judgment.

a. "[T]he exhaustion doctrine continues to exist under the APA to the extent that it is required by statute or by *agency rule* as a prerequisite to judicial review." *Darby* v. *Cisneros*, 509 U.S. 137, 153 (1993) (emphasis added). As petitioners concede (Pet. 25), FDA has promulgated a mandatory exhaustion requirement under which a party "must" submit a petition under 21 C.F.R. 10.25(a) "request[ing] that the Commissioner take or refrain from taking any form of administrative action" before "any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. 10.45(b). The principal exception, not relevant here, is that exhaustion is not required when the agency conducts a regulatory hearing on the matter pursuant to 21 C.F.R. 16.1(b). See 21 C.F.R. 10.45(b).

Petitioners argue that this exhaustion requirement is "unlawful" (Pet. 25), because the APA permits administrative exhaustion requirements only where the "disputed agency action remains inoperative during any intra-agency appeals." Pet. 26; see Pet. 27 (quoting

5 U.S.C. 704). Petitioners are correct that an agency may require administrative appeals as part of exhaustion only if the agency's decision is stayed during such appeal. See 5 U.S.C. 704; *Darby*, 509 U.S. at 152. But that principle has no application here; FDA's regulations require a party to file a citizen petition in the first instance, but they do not require pursuit of administrative appeals before coming to court. See 21 C.F.R. 10.45(e) ("An interested person may request judicial review of a final decision of the Commissioner in the courts *without first petitioning the Commissioner for reconsideration* or for a stay of action," subject to limitations not relevant here.) (emphasis added); see Pet. App. 32a-34a (explaining the relationship between Section 10.45(b)'s exhaustion requirement and Section 10.45(e)'s appeal provisions).

Petitioners also argue (Pet. 30-32) that they did in fact exhaust administrative remedies by virtue of commenting on FDA's ANPRM regarding whether to conduct a rulemaking to clarify FDA's authority to approve a drug for dual prescription and OTC dispensing. Even if such a factbound question merited this Court's review, petitioners' argument is mistaken. The proceeding in which petitioners participated concerned whether to conduct a rulemaking regarding general issues concerning dual Rx and OTC availability. Neither that proceeding—nor even a rulemaking, had FDA undertaken one—would have addressed the specific question petitioners seek to litigate in this case, which is whether Plan B in particular was appropriate for distribution under a dual Rx-and-OTC regime. Accordingly, petitioners' participation in the ANPRM process did not satisfy their obligation to exhaust their administrative remedies before bringing this suit.

Finally, because there is no dispute that petitioners filed no citizen petition, their assertion (Pet. 28-29) that the government bears the burden of proof on exhaustion is beside the point. Whoever bears the burden of proof, it is undisputed that petitioners did not exhaust by filing a citizen petition. And as the courts below correctly found, there is no basis on this record for excusing petitioners' failure to exhaust in this case—and indeed, petitioners never argued in the district court that exhaustion would be futile. See Pet. App. 4a, 36a-37a, 41a-42a.

b. Petitioners suggest (Pet. 33-35) that if the courts below correctly determined that they lacked standing, this Court should grant certiorari to vacate any discussion of the exhaustion issue. As an initial matter, it may not have been improper for the courts below to reach the exhaustion issue in the alternative. Even *Steel Co.* v. *Citizens for a Better Environment*, 523 U.S. 83 (1998)—a case on which petitioners principally rely, see Pet. 34—recognized that the Court has treated exhaustion as jurisdictional in some instances. See 523 U.S. at 100 (discussing *Chandler* v. *Judicial Council of the Tenth Circuit*, 398 U.S. 74, 86 (1970)); but see *Reed Elsevier, Inc.* v. *Muchnick*, 130 S. Ct. 1237, 1246-1247 & n.6 (2010) ("We * * * have treated as nonjurisdictional [some] types of threshold requirements that claimants must complete, or exhaust, before filing a lawsuit."). In any case, this Court "reviews judgments, not statements in opinions." *Black* v. *Cutter Labs.*, 351 U.S. 292, 297 (1956). There would be minimal purpose to granting certiorari merely to affirm the judgment below on a subset of the grounds addressed by the courts below.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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